K061678 JAN 12 2007 1/3

510(k) SUMMARY

ProRhythm, Inc's ProMap Coaxial Mapping Catheter

This 510(k) summary is provided as part of the Premarket Notification for ProRhythm, Inc's ProMap Coaxial Mapping Catheter

Submitter: ProRhythm, Inc
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Contact Person: John J. Talarico

Date Prepared: June 12, 2005

Name of Device: ProMap Coaxial Mapping Catheter

Common or Usual Name: Mapping Catheter

Classification Name: Electrode Recording Catheter 21 CFR 870.1220

Predicate Devices:
Biosense Webster Lasso Deflectable Circular Mapping Catheter
Cardima, Inc Pathfinder Catheter

Intended Use / Indications for Use

Intended Use

The ProRhythm™, Inc. ProMap Coaxial Mapping Catheter is an intra-cardiac electrophysiology recording catheter. The ProMap is designed to be used to record cardiac electrograms for the evaluation of cardiac arrhythmias from endocardial and intravascular sites during invasive cardiac electrophysiology procedures.

The ProRhythm ProMap is to be used with the ProMap Connection Cable.

Indications for Use

The ProRhythm™ ProMap is to be used for the evaluation of cardiac arrhythmias from endocardial and intravascular sites.

The ProMap Coaxial Mapping Catheter is typically used in Electrophysiology clinical procedures.

Contraindications

- This device is contraindicated for use as an ablation catheter.
- This device is contraindicated for use in the ventricles. The retrograde approach is contraindicated because of the risk of entrapping the catheter in the left or valvular apparatus.
- This device is contraindicated for use in patients with:

- **left atrial thrombus**
- **prosthetic heart valves**

Electrophysiology studies are contraindicated when the patient's underlying cardiac disease makes it likely that induced arrhythmias will be extremely difficult to terminate and carry a high risk of death as in the following examples.

- trial thrombus
- Unstable angina
- Myocardial Infarctions within the last two weeks.
- Patients who do not tolerate anticoagulation therapy.
- Previous systemic embolization from the left side of the heart
- Recent history of stroke or transient ischemic attack
- Current systemic infection
- Recent pulmonary emboli
- Known or suspected left atrial myxoma

Technological Characteristics

ProRhythm's ProMap Coaxial Mapping Catheter records pulmonary vein potentials when used with electrophysiology recording equipment. The device has 6 electrodes mounted at the distal end. A passive mechanism at the distal end conforms into the shape of a ring ranging from 15 to 25 mm in diameter. The electrodes are spaced either evenly. The handle at the proximal end of the device allows the device to be manipulated into position within the left atrium. A connector at the proximal end of the device enables connection to the ProMap Connection Cable.

The ProMap Coaxial Mapping Catheter is designed to be inserted through a delivery sheath catheter and into the left atrium to record electro grams. The distal end extends past the delivery sheath catheter and forms into a circular ring that is optimized for use in the pulmonary veins. Electrodes mounted at the distal end and spaced uniformly along the circular ring allow recording of pulmonary vein potentials in the left atrium.

The ProMap Coaxial Mapping Catheter can be withdrawn and reinserted (without excessive friction) while the delivery sheath catheter can be deflected. This enables the electro physiologist to perform other functions through the sheaths lumen, such as contrast injections to obtain venograms.

Performance Data

The ProMap Coaxial Mapping Catheter is tested according to the specifications documented in Design Verification Testing Reports. Pre-clinical in-vivo testing further

provided validation that the device performed as intended. In all instances, the ProMap Coaxial Mapping Catheter functioned as intended and met all pass criteria as expected.

Substantial Equivalence

The ProMap Coaxial Mapping Catheter is as safe and effective as the Biosense Webster circular Lasso™ and the Cardima Pathfinder™ catheter. The ProMap Coaxial Mapping Catheter has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the ProMap Coaxial Mapping Catheter and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ProMap Coaxial Mapping Catheter is as safe and effective as the Biosense Webster circular Lasso™ and the Cardima Pathfinder™ catheter. Thus, the ProMap Coaxial Mapping Catheter is substantially equivalent to the predicate devices in construction, materials, and intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ProRhythm, Inc.
c/o Mr. John J. Talarico
VP QA, Regulatory and Clinical Affairs
105 Comac Street
Ronkonkoma, NY 11779

JAN 12 2007

Re: K061678
Trade Name: ProMap Coaxial Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: January 8, 2007
Received: January 9, 2007

Dear Mr. Talarico:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061678

Device Name: ProMap Coaxial Mapping Catheter

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061678